

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of Alan SOLOMON et al.

Group Art Unit: 1647

Serial No.: 09/316,387

Examiner: S. Turner

Filed: May 21, 1999

For: METHODS FOR AMYLOID REMOVAL USING ANTI-AMYLOID ANTIBODIES**Mail Stop Amendment**

U.S. Patent and Trademark Office

Customer Service Window

Randolph Building

401 Dulany Street

Alexandria, VA 22314

TRANSMITTAL OF RESPONSE

Enclosed are the following documents in supplement to the documents filed December 20, 2005 in connection with the above-identified application:

- ☒ Executed Declaration Under 37 CFR § 1.131
☐ Other:

The fee has been calculated as follows:

| | NO. OF CLAIMS | CLAIMS PREVIOUSLY PAID FOR | EXTRA CLAIMS | RATE | FEE |
|---|------------------|----------------------------------|-----------------|------------|---------------|
| Total Claims | 48 | - 48 = | 0 | x \$50.00 | \$0.00 |
| Independent Claims | 5 | - 5 = | 0 | x \$200.00 | \$0.00 |
| If multiple dependent claims are presented, add \$360.00 | | | | | |
| Total Amendment Fee | | | | | \$0.00 |
| If small entity status is applicable, subtract 50% of Total Amendment Fee | | | | | |
| Other fees: | | | | | \$0.00 |
| TOTAL FEE DUE | | | | | \$0.00 |

- ☐ A check for the total fee is attached.
- ☐ Please charge \$0.00 to Deposit Account No. 50-1283 for the total fee. This paper is being submitted in duplicate.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Respectfully submitted,
COOLEY GODWARD LLP

Dated: 3-6-06

COOLEY GODWARD LLP
ATTN: Patent Group
The Bowen Building
875 15th Street, NW
Suite 800
Washington D.C. 20005-2221

By:

Michael S. Tuscan
Michael S. Tuscan
Reg. No. 43,210

CUSTOMER NUMBER 33522

Tel: (202) 842-7800
Fax: (202) 842-7899



PRIVILEGED AND CONFIDENTIAL

PATENT
Attorney Docket 044137-5025-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|--------------------------------|
| In re Application of: Alan Solomon <i>et al.</i> |) | |
| |) | |
| Application No. 09/316,387 |) | Group Art Unit: 1647 |
| |) | |
| Filed: May 21, 1999 |) | Examiner: Sharon Turner |
| |) | |
| For: Methods for Amyloid Removal Using |) | |
| Anti-amyloid Antibodies |) | |

DECLARATION UNDER 37 C.F.R. § 1.131

We Alan Solomon, Rudi Hrcic and Jonathan Stuart Wall, declare as follows:

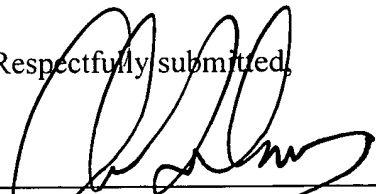
1. We are the named inventors of the above referenced application (Ser. No. 09/316,387).
2. We have read and understand the Office Action of June 20, 2005, in particular the rejection of the pending claims under 35 U.S.C. § 102(e) over U.S. Patent 6,743,427 (the '427 patent) and U.S. Patent 6,787,523 (the '523 patent).
3. We understand that the earliest asserted priority date of the '427 and '523 patents is December 2, 1997 through the priority claim to U.S. Provisional Application Ser. No. 60/067,740.
4. We invented the subject matter of the pending claims before December 2, 1997. In one embodiment, monoclonal antibodies anti-κ1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti-κ8 (31-8c7), deposited as ATCC Acc. No. PTA-103 are disclosed in our U.S. Application Ser. No. 09/316,387.
5. Exhibit A, dated before December 2, 1997, shows that antibodies anti-κ1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti-κ8 (31-8c7), deposited as ATCC Acc. No. PTA-103 bind to different types of amyloid fibrils, including amyloid

fibrils consisting of A β peptide by ELISA analysis (see rows G & H wherein A β 25-35 was incubated with antibody 57-18H12 (Columns 1 & 2) or antibody 31.8c7 (columns 9 & 10)).

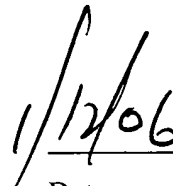
6. Exhibit B, dated before December 2, 1997, shows that antibodies anti- κ 1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti- κ 8 (31-8c7), deposited as ATCC Acc. No. PTA-103 remove amyloidoma masses when administered in an effective amount in a mouse model (see photographs of mice wherein the mice, previously injected with amyloid material, exhibit complete removal of the amyloidoma after administration of the antibody).

7. We each further declare that all statements made herein on our own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

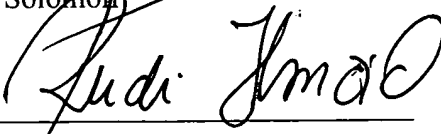
Respectfully submitted,



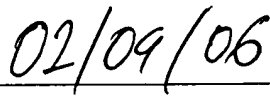
Alan Solomon



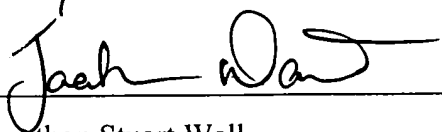
Date



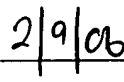
Rudi Hincic



Date



Jonathon Stuart Wall



Date

USING SAME ABS AS [REDACTED] - PREVIOUS RESULTS
GIVEN HERE FOR [REDACTED]

Block : 57-18H12, λ VI, Free K, Free λ , λ VIII, :

25

2mg
g protein
(total)
in
each
well.

Immunoglobulin
 λ VI

14g
KI

910
 λ VI

25-35
Ap.

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|----|----|----|
| A | | 2 | | 2 | | | 2 | 3 | 5 | 6 | 7 | 7 |
| B | 2 | 2 | | 2 | | | 3 | 3 | 6 | 6 | 2 | 2 |
| C | 2 | 3 | | 2 | | | 2 | 2 | 6 | 6 | 1 | 2 |
| D | 2 | 3 | | 2 | | | 2 | 2 | 5 | 6 | 2 | 2 |
| E | 2 | 2 | | 2 | | | 2 | 2 | 4 | 4 | 2 | 2 |
| F | 2 | 2 | | 2 | | | 2 | 2 | 4 | 4 | 2 | 2 |
| G | 2 | 2 | | 2 | | | 2 | 2 | 5 | 5 | 2 | 2 |
| H | 2 | 2 | | 2 | | | 2 | 2 | 5 | 5 | 2 | 2 |

Serum 2,2 shown only

Block 1°
Add Monoclonal
Add

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|----|----|----|
| A | | | | | | | | | | | | |
| B | | | | | | | | | | | | |
| C | | | | | | | | | | | | |
| D | | | | | | | | | | | | |
| E | | | | | | | | | | | | |
| F | | | | | | | | | | | | |
| G | | | | | | | | | | | | |
| H | | | | | | | | | | | | |

26

310 TEK MICROPLATE READER

00008208

ASSAY#

PLATE#

OPERATOR

NOTES

PROGRAM MODE #5

SINGLE WAVELENGTH: 405

TABLE OF ABSORBANCE VALUES

| | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | |
|---|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| A | 0.366 | 0.512 | 0.312 | 0.446 | 0.246 | 0.333 | 0.555 | 0.615 | 1.148 | 1.207 | 0.463 | 0.473 |
| B | 0.424 | 0.484 | 0.353 | 0.445 | 0.290 | 0.330 | 0.690 | 0.668 | 1.177 | 1.248 | 0.493 | 0.524 |
| C | 0.558 | 0.621 | 0.378 | 0.454 | 0.354 | 0.387 | 0.440 | 0.487 | 1.281 | 1.268 | 0.476 | 0.470 |
| D | 0.546 | 0.633 | 0.356 | 0.485 | 0.334 | 0.399 | 0.424 | 0.492 | 1.161 | 1.333 | 0.420 | 0.481 |
| E | 0.419 | 0.486 | 0.340 | 0.434 | 0.271 | 0.287 | 0.485 | 0.485 | 0.943 | 0.993 | 0.419 | 0.409 |
| F | 0.423 | 0.493 | 0.355 | 0.446 | 0.281 | 0.312 | 0.565 | 0.578 | 0.959 | 0.992 | 0.458 | 0.440 |
| G | 0.441 | 0.541 | 0.379 | 0.525 | 0.312 | 0.369 | 0.476 | 0.535 | 1.053 | 1.191 | 0.472 | 0.496 |
| H | 0.457 | 0.549 | 0.393 | 0.505 | 0.310 | 0.364 | 0.499 | 0.500 | 1.119 | 1.178 | 0.474 | 0.499 |

BEST AVAILABLE COPY

27

TABLE OF RANGES

BIN # : 0 1 2 3 4 5 6 7 8 9
 RANGES: 0.000 0.200 0.400 0.600 0.800 1.000 1.200 1.400 1.600 1.800 2.000

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|----|----|----|
| A | 1 | 2 | 1 | 2 | 1 | 1 | 2 | 3 | 5 | 6 | 2 | 2 |
| B | 2 | 2 | 1 | 2 | 1 | 1 | 3 | 3 | 6 | 6 | 2 | 2 |
| C | 2 | 3 | 1 | 2 | 1 | 1 | 2 | 2 | 6 | 6 | 2 | 2 |
| D | 2 | 3 | 1 | 2 | 1 | 1 | 2 | 2 | 5 | 6 | 2 | 2 |
| E | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 | 4 | 4 | 2 | 2 |
| F | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 | 4 | 4 | 2 | 2 |
| G | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 | 5 | 5 | 2 | 2 |
| H | 2 | 2 | 1 | 2 | 1 | 1 | 2 | 2 | 5 | 5 | 2 | 2 |